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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,114	03/22/2001	Michael L. Boyer II	8932-208-999	2083

20582 7590 10/07/2002

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EXAMINER

HAMILTON, LALITA M

ART UNIT PAPER NUMBER

3764

DATE MAILED: 10/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

**Office Action Summary**

Application No.

09/814,114

Applicant(s)

BOYER ET AL.

Examiner

Lalita M Hamilton

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 14-15, 18, 20, 41, 53, and 55 are rejected under 35

U.S.C. 102(a) as being anticipated by Boyce (5,899,939).

Boyce discloses a implant comprising inner and outer sheaths formed from different bone wherein the exterior surface of the outer sheath contacts the interior surface of no more than one other sheath (fig.2: 22 and 23), the contacting surfaces of adjacent sheaths being machined surfaces (col.4, lines 47-52), at least one sheath packing bone growth materials (col.2, lines 35-40 and col.5, lines 18-20), two layers of bone components couple to each other at a securing region and at least one insertable securing element (col.4, lines 10-20), and the outer surface separated from a portion of the inner surface.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 2, 5-13, 17, 19, 21-22, 25-39, 42-43, 48-52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce.

Boyce discloses an alternative embodiment comprising a core disposed in the inner sheath (fig.1) and that the implant may be made of different materials other than cortical bone (col.6, lines 3-6). Boyce further discloses bones comprising autograft, allograft, and xenograft bone tissue (col.1: 19 and col.3, lines 40-43), partially demineralized and demineralized bone tissue (col.3, lines 43-44), a cross section of the sheaths and core, sheaths coupled together with at least one fastener (col.4, lines 10-15) by means of a screw or pin, wherein the fastener intersects each of the sheaths and core (col.4, lines 15-20), the sheaths and core bonded by a bonding agent (col.4, line 10), the inner and outer sheaths and core being at least partially dehydrated (col.6, lines 48-58), the contacting surfaces of adjacent sheaths being machined surfaces (col.4, lines 48-52), and the material of a supplemental sheath formed of ceramics, polymers, and other composites (col.4, lines 24-33); however, Boyce does not disclose alignment indicia. It would have been obvious to one having ordinary skill in the art to incorporate a core into the device as an alternative embodiment as disclosed by Boyce.

The alignment indicia is being treated as a choice of design, since Boyce discloses the sheaths aligned. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate alignment indicia onto the device disclosed by Boyce as an alternative means of allowing one to precisely align the sheaths.

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Claims 3-4, 16, 23-24, 40, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in view of McIntyre (4,950,296).

Boyce discloses the invention substantially as claimed; however, Boyce does not disclose cancellous bone or bones selected from the femur, tibia, humerus, fibula, ulna, and radius. McIntyre teaches a bone implant comprising cancellous bone (col.3, lines 15-16) and bones selected from the femur, tibia, humerus, fibula, ulna, and radius. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate cancellous bone and bones selected from the femur, tibia, humerus, fibula, ulna, and radius taught by McIntyre as alternative choices of materials for the device disclosed by Boyce.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tormala (5,084,051), Fox (4,936,851), Boyce (6,123,731), and Gogolewski (5,676,699) teach implants.

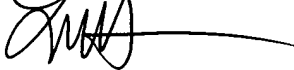
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is

(703) 305-2272.



LMH



**NICHOLAS D. LUCCHESI**  
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**TECHNOLOGY CENTER 3700**

September 30, 2002